special enrollment is not a waiting period. If an individual seeks and obtains coverage in the individual market, any period after the date the individual files a substantially complete application for coverage and before the first day of coverage is a waiting period.

[62 FR 16955, Apr. 8, 1997; 62 FR 31670, 31693, June 10, 1997]

Subpart B [Reserved]

PART 145 [RESERVED]

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

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AUTHORITY: Secs. 2701 through 2763, 2791, and 2792 of the PHS Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

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Subpart A—General Provisions

§ 146.101 Basis and scope.

(a) *Statutory basis.* This part implements sections 2701 through 2723 of the PHS Act. Its purpose is to improve access to group health insurance coverage and to guarantee the renewability of all coverage in the group market. Sections 2791 and 2792 of the PHS Act define terms used in the regulations in this subchapter and provide the basis for issuing these regulations, respectively.

(b) *Scope.* A group health plan or health insurance issuer offering group health insurance coverage may provide greater rights to participants and beneficiaries than those set forth in this part.

(1) *Subpart B.* Subpart B of this part sets forth minimum requirements for group health plans and health insurance issuers offering group health insurance coverage concerning:

(i) Limitations on a preexisting condition exclusion period.

(ii) Certificates and disclosure of previous coverage.

(iii) Methods of counting creditable coverage.

(iv) Special enrollment periods.

(v) Use of an affiliation period by an HMO as an alternative to a preexisting condition exclusion.

(2) *Subpart D.* Subpart D of this part sets forth exceptions to the requirements of Subpart B for certain plans and certain types of benefits.

(3) *Subpart E.* Subpart E of this part implements sections 2711 through 2713 of the PHS Act, which set forth requirements that apply only to health insurance issuers offering health insurance coverage in connection with a group health plan.

(4) *Subpart F.* Subpart F of this part addresses the treatment of non-Federal governmental plans, and sets forth enforcement procedures.

Subpart B—Requirements Relating to Access and Renewability of Coverage, and Limitations on Preexisting Condition Exclusion Periods

§ 146.111 Limitations on preexisting condition exclusion periods.

(a) *Preexisting condition exclusion*—(1) *General.* Subject to paragraph (b) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may impose, with respect to a participant or beneficiary, a preexisting condition exclusion only if the requirements of this paragraph (a) are satisfied.

(1)(i) *6-month look-back rule.* A preexisting condition exclusion must relate to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period ending on the enrollment date.

(A) For purposes of this paragraph (a)(1)(i), medical advice, diagnosis, care, or treatment is taken into account only if it is recommended by, or received from, an individual licensed or similarly authorized to provide such services under State law and operating within the scope of practice authorized by State law.

(B) For purposes of this paragraph (a)(1)(i), the 6-month period ending on the enrollment date begins on the 6-month anniversary date preceding the enrollment date. For example, for an enrollment date of August 1, 1998, the 6-month period preceding the enrollment date is the period commencing on February 1, 1998 and continuing through July 31, 1998. As another example, for an enrollment date of August 30, 1998, the 6-month period preceding the enrollment date is the period commencing on February 28, 1998 and continuing through August 29, 1998.

(C) The following examples illustrate the requirements of this paragraph (a)(1)(i):

Example 1: (i) Individual *A* is treated for a medical condition 7 months before the enrollment date in Employer *R*'s group health plan. As part of such treatment, *A*'s physician recommends that a follow-up examination be given 2 months later. Despite this recommendation, *A* does not receive a follow-up examination and no other medical advice, diagnosis, care, or treatment for that condition is recommended to *A* or received by *A* during the 6-month period ending on *A*'s enrollment date in Employer *R*'s plan.

(ii) In this *Example,* Employer *R*'s plan may not impose a preexisting condition exclusion period with respect to the condition for which *A* received treatment 7 months prior to the enrollment date.

Example 2: (i) Same facts as *Example 1* except that Employer *R*'s plan learns of the condition and attaches a rider to *A*'s policy excluding coverage for the condition. Three months after enrollment, *A*'s condition recurs, and Employer *R*'s plan denies payment under the rider.

(ii) In this *Example,* the rider is a preexisting condition exclusion and Employer *R*'s plan may not impose a preexisting condition exclusion with respect to the condition for which *A* received treatment 7 months prior to the enrollment date.

Example 3: (i) Individual *B* has asthma and is treated for that condition several times during the 6-month period before *B*'s enrollment date in Employer *S*'s plan. The plan imposes a 12-month preexisting condition exclusion. *B* has no prior creditable coverage to reduce the exclusion period. Three months after the enrollment date, *B* begins coverage under Employer *S*'s plan. *B* is hospitalized for asthma.

(ii) In this *Example,* Employer *S*'s plan may exclude payment for the hospital stay and the physician services associated with this illness because the care is related to a medical condition for which treatment was received by *B* during the 6-month period before the enrollment date.

Example 4: (i) Individual *D,* who is subject to a preexisting condition exclusion imposed by Employer *U*'s plan, has diabetes, as well as a foot condition caused by poor circulation and retinal degeneration (both of which are conditions that may be directly attributed to diabetes). After enrolling in the plan, *D* stumbles and breaks a leg.

(ii) In this *Example,* the leg fracture is not a condition related to *D*'s diabetes, even though poor circulation in *D*'s extremities and poor vision may have contributed towards the accident. However, any additional medical services that may be needed because of *D*'s preexisting diabetic condition that would not be needed by another patient with a broken leg who does not have diabetes may be subject to the preexisting condition exclusion imposed under Employer *U*'s plan.

(ii) *Maximum length of preexisting condition exclusion (the look-forward rule).* A preexisting condition exclusion is not permitted to extend for more than 12 months (18 months in the case of a late enrollee) after the enrollment date. For purposes of this paragraph (a)(1)(ii), the 12-month and 18-month periods after the enrollment date are determined by reference to the anniversary of the enrollment date. For example, for an enrollment date of August 1, 1998, the 12-month period after the enrollment date is the period commencing on August 1, 1998 and continuing through July 31, 1999.

(iii) *Reducing a preexisting condition exclusion period by creditable coverage.* The period of any preexisting condition exclusion that would otherwise apply to an individual under a group health plan is reduced by the number of days of creditable coverage the individual has as of the enrollment date, as counted under §146.113. For purposes of this part, the phrase ''days of creditable coverage'' has the same meaning as the phrase ''the aggregate of the periods of creditable coverage'' as such phrase is used in section 2701(a)(3) of the PHS Act.

(iv) *Other standards.* See §146.121 for other standards that may apply with respect to certain benefit limitations or restrictions under a group health plan.

(2) *Enrollment definitions*—(i) *Enrollment date* means the first day of coverage or, if there is a waiting period, the first day of the waiting period.

(ii) (A) *First day of coverage* means, in the case of an individual covered for benefits under a group health plan in the group market, the first day of coverage under the plan and, in the case of an individual covered by health insurance coverage in the individual market, the first day of coverage under the policy.

(B) *Example.* The following example illustrates the requirements of paragraph (a)(2)(ii)(A) of this section:

Example: (i) Employer *V*'s group health plan provides for coverage to begin on the first day of the first payroll period following the date an employee is hired and completes the applicable enrollment forms, or on any subsequent January 1 after completion of the applicable enrollment forms. Employer *V*'s plan imposes a preexisting condition exclusion for 12 months (reduced by the individual's creditable coverage) following an individual's enrollment date. Employee *E* is hired by Employer *V* on October 13, 1998 and then on October 14, 1998 completes and files all the forms necessary to enroll in the plan. *E*'s coverage under the plan becomes effective on October 25, 1998 (which is the beginning of the first payroll period after *E*'s date of hire).

(ii) In this *Example, E*'s enrollment date is October 13, 1998 (which is the first day of the waiting period for *E*'s enrollment and is also *E*'s date of hire). Accordingly, with respect to *E,* the 6-month period in paragraph (a)(1)(i) would be the period from April 13, 1998 through October 12, 1998, the maximum permissible period during which Employer *V*'s plan could apply a preexisting condition exclusion under paragraph (a)(1)(ii) would be the period from October 13, 1998 through October 12, 1999, and this period would be reduced under paragraph (a)(1)(iii) by *E*'s days of creditable coverage as of October 13, 1998.

(iii) *Late enrollee* means an individual whose enrollment in a plan is a late enrollment.

(iv) *Late enrollment* means enrollment under a group health plan other than on—

(A) The earliest date on which coverage can become effective under the terms of the plan; or

(B) A special enrollment date for the individual. If an individual ceases to be eligible for coverage under the plan by terminating employment, and subsequently becomes eligible for coverage under the plan by resuming employment, only eligibility during the individual's most recent period of employment is taken into account in determining whether the individual is a late enrollee under the plan with respect to the most recent period of coverage. Similar rules apply if an individual again becomes eligible for coverage following a suspension of coverage that applied generally under the plan.

(v) *Examples.* The following examples illustrate the requirements of this paragraph (a)(2):

Example 1: (i) Employee *F* first becomes eligible to be covered by Employer *W*'s group health plan on January 1, 1999, but elects not to enroll in the plan until April 1, 1999. April 1, 1999 is not a special enrollment date for *F*.

(ii) In this *Example, F* would be a late enrollee with respect to *F*'s coverage that became effective under the plan on April 1, 1999.

Example 2: (i) Same as *Example 1,* except that *F* does not enroll in the plan on April 1, 1999 and terminates employment with Employer *W* on July 1, 1999, without having had any health insurance coverage under the plan. *F* is rehired by Employer *W* on January 1, 2000 and is eligible for and elects coverage under Employer *W*'s plan effective on January 1, 2000.

(ii) In this *Example, F* would not be a late enrollee with respect to *F*'s coverage that became effective on January 1, 2000.

(b) *Exceptions pertaining to preexisting condition exclusions*—(1) *Newborns*—(i) *General rule.* Subject to paragraph (b)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion with regard to a child who, as of the last day of the 30-day period beginning with the date of birth, is covered under any creditable coverage. Accordingly, if a newborn is enrolled in a group health plan (or other creditable coverage) within 30 days after birth and subsequently enrolls in another group health plan without a significant break in coverage, the other plan may not impose any preexisting condition exclusion with regard to the child.

(ii) *Example.* The following example illustrates the requirements of this paragraph (b)(1):

Example: (i) Seven months after enrollment in Employer *W*'s group health plan, Individual *E* has a child born with a birth defect. Because the child is enrolled in Employer *W*'s plan within 30 days of birth, no preexisting condition exclusion may be imposed with respect to the child under Employer *W*'s plan. Three months after the child's birth, *E* commences employment with Employer *X* and enrolls with the child in Employer *X*'s plan within 45 days of leaving Employer *W*'s plan. Employer *X*'s plan imposes a 12-month exclusion for any preexisting condition.

(ii) In this *Example,* Employer *X*'s plan may not impose any preexisting condition exclusion with respect to *E*'s child because the child was covered within 30 days of birth and had no significant break in coverage. This result applies regardless of whether *E*'s child is included in the certificate of creditable coverage provided to *E* by Employer *W* indicating 300 days of dependent coverage or receives a separate certificate indicating 90 days of coverage. Employer *X*'s plan may impose a preexisting condition exclusion with respect to *E* for up to 65 days for any preexisting condition of *E* for which medical advice, diagnosis, care, or treatment was recommended or received by *E* within the 6-month period ending on *E*'s enrollment date in Employer *X*'s plan.

(2) *Adopted children.* Subject to paragraph (b)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. This rule does not apply to coverage before the date of such adoption or placement for adoption.

(3) *Break in coverage.* Paragraphs (b)(1) and (b)(2) of this section no longer apply to a child after a significant break in coverage.

(4) *Pregnancy.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not impose a preexisting condition exclusion relating to pregnancy as a preexisting condition.

(5) *Special enrollment dates.* For special enrollment dates relating to new dependents, see § 146.117(b).

(c) *Notice of plan's preexisting condition exclusion.* A group health plan, and a health insurance issuer offering group health insurance under the plan, may not impose a preexisting condition exclusion with respect to a participant or dependent of the participant before notifying the participant, in writing, of the existence and terms of any preexisting condition exclusion under the plan and of the rights of individuals to demonstrate creditable coverage (and any applicable waiting periods) as required by § 146.115. The description of the rights of individuals to demonstrate creditable coverage includes a description of the right of the individual to request a certificate from a prior plan or issuer, if necessary, and a statement that the current plan or issuer will assist in obtaining a certificate from any prior plan or issuer, if necessary.

(Approved by the Office of Management and Budget under control number 0938–0702.)

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§ 146.113 Rules relating to creditable coverage.

(a) *General rules*—(1) *Creditable coverage.* For purposes of this section, except as provided in paragraph (a)(2), the term creditable coverage means coverage of an individual under any of the following:

(i) A group health plan as defined in § 144.103.

(ii) Health insurance coverage as defined in § 144.103 (whether or not the entity offering the coverage is subject to the requirements of this part and 45 CFR part 148, and without regard to whether the coverage is offered in the group market, the individual market, or otherwise).

(iii) Part A or part B of title XVIII of the Social Security Act (Medicare).

(iv) Title XIX of the Social Security Act (Medicaid), other than coverage consisting solely of benefits under section 1928 of the Social Security Act (the program for distribution of pediatric vaccines).

(v) Title 10 U.S.C. Chapter 55 (medical and dental care for members and certain former members of the uniformed services, and for their dependents; for purposes of title 10 U.S.C. chapter 55, *uniformed services* means the armed forces and the Commissioned Corps of the National Oceanic and Atmospheric Administration and of the Public Health Service).

(vi) A medical care program of the Indian Health Service or of a tribal organization.

(vii) A State health benefits risk pool. For purposes of this section, a State health benefits risk pool means—

(A) An organization qualifying under section 501(c)(26) of the Code;

(B) A qualified high risk pool described in section 2744(c)(2) of the PHS Act; or

(C) Any other arrangement sponsored by a State, the membership composition of which is specified by the State and which is established and maintained primarily to provide health insurance coverage for individuals who are residents of such State and who, by reason of the existence or history of a medical condition—

(*1*) Are unable to acquire medical care coverage for such condition through insurance or from an HMO; or

(*2*) Are able to acquire such coverage only at a rate which is substantially in excess of the rate for such coverage through the membership organization.

(viii) A health plan offered under title 5 U.S.C. chapter 89 (the Federal Employees Health Benefits Program).

(ix) A public health plan. For purposes of this section, a public health plan means any plan established or maintained by a State, county, or other political subdivision of a State that provides health insurance coverage to individuals who are enrolled in the plan.

(x) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

(2) *Excluded coverage.* Creditable coverage does not include coverage consisting solely of coverage of excepted benefits (described in § 146.145).

(3) *Methods of counting creditable coverage.* For purposes of reducing any preexisting condition exclusion period, as provided under § 146.111(a)(1)(iii), a group health plan, and a health insurance issuer offering group health insurance coverage, determines the amount of an individual's creditable coverage by using the standard method described in paragraph (b), except that the plan, or issuer, may use the alternative method under paragraph (c) with respect to any or all of the categories of benefits described under paragraph (c)(3).

(b) *Standard method*—(1) *Specific benefits not considered.* Under the standard method, a group health plan, and a health insurance issuer offering group health insurance coverage, determines the amount of creditable coverage without regard to the specific benefits included in the coverage.

(2) *Counting creditable coverage*—(i) *Based on days.* For purposes of reducing the preexisting condition exclusion period, a group health plan, and a health insurance issuer offering group health insurance coverage, determines the amount of creditable coverage by counting all the days that the individual has under one or more types of creditable coverage. Accordingly, if on a particular day, an individual has creditable coverage from more than one source, all the creditable coverage

on that day is counted as one day. Further, any days in a waiting period for a plan or policy are not creditable coverage under the plan or policy.

(ii) *Days not counted before significant break in coverage.* Days of creditable coverage that occur before a significant break in coverage are not required to be counted.

(iii) *Definition of significant break in coverage.* A significant break in coverage means a period of 63 consecutive days during all of which the individual does not have any creditable coverage, except that neither a waiting period nor an affiliation period is taken into account in determining a significant break in coverage. (See section 731(b)(2)(iii) of ERISA and section 2723(b)(2)(iii) of the PHS Act, which exclude from preemption State insurance laws that require a break of more than 63 days before an individual has a significant break in coverage for purposes of State law.)

(iv) *Examples.* The following examples illustrate how creditable coverage is counted in reducing preexisting condition exclusion periods:

Example 1: (i) Individual *A* works for Employer *P* and has creditable coverage under Employer *P*'s plan for 18 months before *A*'s employment terminates. *A* is hired by Employer *O*, and enrolls in Employer *O*'s group health plan, 64 days after the last date of coverage under Employer *P*'s plan. Employer *O*'s plan has a 12-month preexisting condition exclusion period.

(ii) In this *Example,* because *A* had a break in coverage of 63 days, Employer *O*'s plan may disregard *A*'s prior coverage and *A* may be subject to a 12-month preexisting condition exclusion period.

Example 2: (i) Same facts as *Example 1,* except that *A* is hired by Employer *O,* and enrolls in Employer *O*'s plan, on the 63rd day after the last date of coverage under Employer *P*'s plan.

(ii) In this *Example, A* has a break in coverage of 62 days. Because *A*'s break in coverage is not a significant break in coverage, Employer *O*'s plan must count *A*'s prior creditable coverage for purposes of reducing the plan's preexisting condition exclusion period as it applies to *A.*

Example 3: (i) Same facts as *Example 1,* except that Employer *O*'s plan provides benefits through an insurance policy that, as required by applicable State insurance laws, defines a significant break in coverage as 90 days.

(ii) In this *Example,* the issuer that provides group health insurance to Employer *O's* plan must count *A's* period of creditable coverage prior to the 63-day break.

Example 4: (i) Same facts as *Example 3,* except that Employer *O*'s plan is a self-insured plan, and thus is not subject to State insurance laws.

(ii) In this *Example,* the plan is not governed by the longer break rules under State insurance law and *A*'s previous coverage may be disregarded.

Example 5: (i) Individual *B* begins employment with Employer *R* 45 days after terminating coverage under a prior group health plan. Employer *R*'s group health plan has a 30-day waiting period before coverage begins. *B* enrolls in Employer *R*'s plan when first eligible.

(ii) In this *Example, B* does not have a significant break in coverage for purposes of determining whether *B*'s prior coverage must be counted by Employer *R*'s plan. *B* has only a 44-day break in coverage because the 30-day waiting period is not taken into account in determining a significant break in coverage.

Example 6: (i) Individual *C* works for Employer *S* and has creditable coverage under Employer *S*'s plan for 200 days before *C*'s employment is terminated and coverage ceases. *C* is then unemployed and does not have any creditable coverage for 51 days before being hired by Employer *T*. Employer *T*'s plan has a 3-month waiting period. *C* works for Employer *T* for 2 months and then terminates employment. Eleven days after terminating employment with Employer *T, C* begins working for Employer *U*. Employer *U*'s plan has no waiting period, but has a 6-month preexisting condition exclusion period.

(ii) In this *Example, C* does not have a significant break in coverage because, after disregarding the waiting period under Employer *T*'s plan, *C* had only a 62-day break in coverage (51 days plus 11 days). Accordingly, *C* has 200 days of creditable coverage and Employer *U*'s plan may not apply its 6-month preexisting condition exclusion period with respect to *C.*

Example 7: (i) Individual *D* terminates employment with Employer *V* on January 13, 1998 after being covered for 24 months under Employer *V*'s group health plan. On March 17, the 63rd day without coverage, *D* applies for a health insurance policy in the individual market. *D*'s application is accepted and the coverage is made effective May 1.

(ii) In this *Example,* because *D* applied for the policy before the end of the 63rd day, and coverage under the policy ultimately became effective, the period between the date of application and the first day of coverage is a waiting period, and no significant break in coverage occurred even though the actual period without coverage was 107 days.

Example 8: (i) Same facts as *Example 7,* except that *D*'s application for a policy in the individual market is denied.

(ii) In this *Example*, because *D* did not obtain coverage following application, *D* incurred a significant break in coverage on the 64th day.

(v) *Other permissible counting methods*—(A) *General rule.* Notwithstanding any other provisions of this paragraph (b)(2), for purposes of reducing a preexisting condition exclusion period (but not for purposes of issuing a certificate under § 146.115), a group health plan, and a health insurance issuer offering group health insurance coverage, may determine the amount of creditable coverage in any other manner that is at least as favorable to the individual as the method set forth in this paragraph (b)(2), subject to the requirements of other applicable law.

(B) *Example.* The following example illustrates the requirements of this paragraph (b)(2)(v):

Example: (i) Individual F has coverage under Group Health Plan *Y* from January 3, 1997 through March 25, 1997. *F* then becomes covered by Group Health Plan *Z*. *F*'s enrollment date in Plan *Z* is May 1, 1997. Plan *Z* has a 12-month preexisting condition exclusion period.

(ii) In this *Example*, Plan *Z* may determine, in accordance with the rules prescribed in paragraph (b)(2) (i), (ii), and (iii), that *F* has 82 days of creditable coverage (29 days in January, 28 days in February, and 25 days in March). Thus, the preexisting condition exclusion period will no longer apply to *F* on February 8, 1998 (82 days before the 12-month anniversary of *F*'s enrollment (May 1)). For administrative convenience, however, Plan *Z* may consider that the preexisting condition exclusion period will no longer apply to *F* on the first day of the month (February 1).

(c) *Alternative method*—(1) *Specific benefits considered.* Under the alternative method, a group health plan, or a health insurance issuer offering group health insurance coverage, determines the amount of creditable coverage based on coverage within any category of benefits described in paragraph (c)(3) and not based on coverage for any other benefits. The plan or issuer may use the alternative method for any or all of the categories. The plan may apply a different preexisting condition exclusion period with respect to each category (and may apply a different preexisting condition exclusion period for benefits that are not within any category). The creditable coverage determined for a category of benefits applies only for purposes of reducing the preexisting condition exclusion period with respect to that category. An individual's creditable coverage for benefits that are not within any category for which the alternative method is being used is determined under the standard method of paragraph (b) of this section.

(2) *Uniform application.* A plan or issuer using the alternative method is required to apply it uniformly to all participants and beneficiaries under the plan or policy. The use of the alternative method is set forth in the plan.

(3) *Categories of benefits.* The alternative method for counting creditable coverage may be used for coverage for any of the following categories of benefits:

(i) Mental health.

(ii) Substance abuse treatment.

(iii) Prescription drugs.

(iv) Dental care.

(v) Vision care.

(4) *Plan notice.* If the alternative method is used, the plan is required to—

(i) State prominently that the plan is using the alternative method of counting creditable coverage in disclosure statements concerning the plan, and state this to each enrollee at the time of enrollment under the plan; and

(ii) Include in these statements a description of the effect of using the alternative method, including an identification of the categories used.

(5) *Issuer notice.* With respect to health insurance coverage offered by an issuer in the small or large group market, if the insurance coverage uses the alternative method, the issuer states prominently in any disclosure statement concerning the coverage, and to each employer at the time of the offer or sale of the coverage, that the issuer is using the alternative method, and includes in such statements a description of the effect of using the alternative method. This applies separately to each type of coverage offered by the health insurance issuer.

(6) *Disclosure of information on previous benefits.* See § 146.115(b) for special rules concerning disclosure of coverage to a plan, or issuer, using the alternative method of counting creditable coverage under this paragraph (c).

(7) *Counting creditable coverage*—(i) *General.* Under the alternative method, the group health plan or issuer counts creditable coverage within a category if any level of benefits is provided within the category. Coverage under a reimbursement account or arrangement, such as a flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code), does not constitute coverage within any category.

(ii) *Special rules.* In counting an individual's creditable coverage under the alternative method, the group health plan, or issuer, first determines the amount of the individual's creditable coverage that may be counted under paragraph (b) of this section, up to a total of 365 days of the most recent creditable coverage (546 days for a late enrollee). The period over which this creditable coverage is determined is referred to as the ''determination period.'' Then, for the category specified under the alternative method, the plan or issuer counts within the category all days of coverage that occurred during the determination period (whether or not a significant break in coverage for that category occurs), and reduces the individual's preexisting condition exclusion period for that category by that number of days. The plan or issuer may determine the amount of creditable coverage in any other reasonable manner, uniformly applied, that is at least as favorable to the individual.

(iii) *Example.* The following example illustrates the requirements of this paragraph (c)(7):

Example: (i) Individual *D* enrolls in Employer *V*'s plan on January 1, 2001. Coverage under the plan includes prescription drug benefits. On April 1, 2001, the plan ceases providing prescription drug benefits. *D*'s employment with Employer *V* ends on January 1, 2002, after *D* was covered under Employer *V*'s group health plan for 365 days. *D* enrolls in Employer *Y*'s plan on February 1, 2001 (*D*'s enrollment date). Employer *Y*'s plan uses the alternative method of counting creditable coverage and imposes a 12-month preexisting condition exclusion on prescription drug benefits.

(ii) In this *Example,* Employer *Y*'s plan may impose a 275-day preexisting condition exclusion with respect to *D* for prescription drug benefits because *D* had 90 days of creditable coverage relating to prescription drug benefits within *D*'s determination period.

[62 FR 16958, Apr. 8, 1997; 62 FR 31670, 31693, June 10, 1997]

§ 146.115 Certification and disclosure of previous coverage.

(a) *Certificate of creditable coverage*—(1) *Entities required to provide certificate*—(i) *General.* A group health plan, and each health insurance issuer offering group health insurance coverage under a group health plan, is required to furnish certificates of creditable coverage in accordance with this paragraph (a).

(ii) *Duplicate certificates not required.* An entity required to provide a certificate under this paragraph (a)(1) for an individual is deemed to have satisfied the certification requirements for that individual if another party provides the certificate, but only to the extent that information relating to the individual's creditable coverage and waiting or affiliation period is provided by the other party. For example, in the case of a group health plan funded through an insurance policy, the issuer is deemed to have satisfied the certification requirement with respect to a participant or beneficiary if the plan actually provides a certificate that includes the information required under paragraph (a)(3) of this section with respect to the participant or beneficiary.

(iii) *Special rule for group health plans.* To the extent coverage under a plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirements under this paragraph (a)(1) if any issuer offering the coverage is required to provide the certificates pursuant to an agreement between the plan and the issuer. For example, if there is an agreement between an issuer and the plan sponsor under which the issuer agrees to provide certificates for individuals covered under the plan, and the issuer fails to provide a certificate to an individual when the plan would have been required to provide one under this paragraph (a), then the issuer, but not

the plan, violates the certification requirements of this paragraph (a).

(iv) *Special rules for issuers*—(A) *Responsibility of issuer for coverage period*—(*1*) *General rule.* An issuer is not required to provide information regarding coverage provided to an individual by another party.

(2) *Example.* The following example illustrates the requirements of this paragraph (a)(1)(iv)(A):

Example. (i) A plan offers coverage with an HMO option from one issuer and an indemnity option from a different issuer. The HMO has not entered into an agreement with the plan to provide certificates as permitted under paragraph (a)(1)(iii) of this section.

(ii) In this *Example,* if an employee switches from the indemnity option to the HMO option and later ceases to be covered under the plan, any certificate provided by the HMO is not required to provide information regarding the employee's coverage under the indemnity option.

(B) *Cessation of issuer coverage prior to cessation of coverage under a plan*—(*1*) *General rule.* If an individual's coverage under an issuer's policy ceases before the individual's coverage under the plan ceases, the issuer is required to provide sufficient information to the plan (or to another party designated by the plan) to enable a certificate to be provided by the plan (or other party), after cessation of the individual's coverage under the plan, that reflects the period of coverage under the policy. The provision of that information to the plan will satisfy the issuer's obligation to provide an automatic certificate for that period of creditable coverage for the individual under paragraphs (a)(2)(ii) and (a)(3) of this section. In addition, an issuer providing that information is required to cooperate with the plan in responding to any request made under paragraph (b)(1) of this section (relating to the alternative method of counting creditable coverage). If the individual's coverage under the plan ceases at the time the individual's coverage under the issuer's policy ceases, the issuer must provide an automatic certificate under paragraph (a)(2)(ii) of this section. An issuer may presume that an individual whose coverage ceases at a time other than the effective date for changing enrollment options has ceased to be covered under the plan.

(*2*) *Example.* The following example illustrates the requirements of this paragraph (a)(1)(iv)(B):

Example: (i) A group health plan provides coverage under an HMO option and an indemnity option with a different issuer, and only allows employees to switch on each January 1. Neither the HMO nor the indemnity issuer has entered into an agreement with the plan to provide certificates as permitted under paragraph (a)(1)(iii) of this section.

(ii) In this *Example,* if an employee switches from the indemnity option to the HMO option on January 1, the issuer must provide the plan (or a person designated by the plan) with appropriate information with respect to the individual's coverage with the indemnity issuer. However, if the individual's coverage with the indemnity issuer ceases at a date other than January 1, the issuer is instead required to provide the individual with an automatic certificate.

(2) *Individuals for whom a certificate must be provided; timing of issuance*—(i) *Individuals.* A certificate must be provided, without charge, for participants or dependents who are or were covered under a group health plan upon the occurrence of any of the events described in paragraph (a)(2)(ii) or (a)(2)(iii) of this section.

(ii) *Issuance of automatic certificates.* The certificates described in this paragraph (a)(2)(ii) are referred to as ''automatic certificates.''

(A) *Qualified beneficiaries upon a qualifying event.* In the case of an individual who is a qualified beneficiary (as defined in section 607(3) of ERISA, section 4980B(g)(1) of the Code, or section 2208 of the PHS Act) entitled to elect COBRA continuation coverage, an automatic certificate is required to be provided at the time the individual would lose coverage under the plan in the absence of COBRA continuation coverage or alternative coverage elected instead of COBRA continuation coverage. A plan or issuer satisfies this requirement if it provides the automatic certificate no later than the time a notice is required to be furnished for a qualifying event under section 606 of ERISA, section 4980B(f)(6) of the Code and section 2206 of the PHS Act (relating to notices required under COBRA).

(B) *Other individuals when coverage ceases.* In the case of an individual who is not a qualified beneficiary entitled to elect COBRA continuation coverage,

an automatic certificate is required to be provided at the time the individual ceases to be covered under the plan. A plan or issuer satisfies this requirement if it provides the automatic certificate within a reasonable time period thereafter. In the case of an individual who is entitled to elect to continue coverage under a State program similar to COBRA and who receives the automatic certificate not later than the time a notice is required to be furnished under the State program, the certificate is deemed to be provided within a reasonable time period after the cessation of coverage under the plan.

(C) *Qualified beneficiaries when COBRA ceases.* In the case of an individual who is a qualified beneficiary and has elected COBRA continuation coverage (or whose coverage has continued after the individual became entitled to elect COBRA continuation coverage), an automatic certificate is to be provided at the time the individual's coverage under the plan ceases. A plan, or issuer, satisfies this requirement if it provides the automatic certificate within a reasonable time after coverage ceases (or after the expiration of any grace period for nonpayment of premiums). An automatic certificate is required to be provided to such an individual regardless of whether the individual has previously received an automatic certificate under paragraph (a)(2)(ii)(A) of this section.

(iii) *Any individual upon request.* Requests for certificates are permitted to be made by, or on behalf of, an individual within 24 months after coverage ceases. Thus, for example, a plan in which an individual enrolls may, if authorized by the individual, request a certificate of the individual's creditable coverage on behalf of the individual from a plan in which the individual was formerly enrolled. After the request is received, a plan or issuer is required to provide the certificate by the earliest date that the plan or issuer, acting in a reasonable and prompt fashion, can provide the certificate. A certificate is to be provided under this paragraph (a)(2)(iii) even if the individual has previously received a certificate under this paragraph (a)(2)(iii) or an automatic certificate under paragraph (a)(2)(ii) of this section.

(iv) *Examples.* The following examples illustrate the requirements of this paragraph (a)(2):

Example 1: (i) Individual *A* terminates employment with Employer *O*. *A* is a qualified beneficiary entitled to elect COBRA continuation coverage under Employer *O*'s group health plan. A notice of the rights provided under COBRA is typically furnished to qualified beneficiaries under the plan within 10 days after a covered employee terminates employment.

(ii) In this *Example,* the automatic certificate may be provided at the same time that *A* is provided the COBRA notice.

Example 2: (i) Same facts as *Example 1,* except that the automatic certificate for *A* is not completed by the time the COBRA notice is furnished to *A.*

(ii) In this *Example,* the automatic certificate may be provided within the period permitted by law for the delivery of notices under COBRA.

Example 3: (i) Employer *R* maintains an insured group health plan. *R* has never had 20 employees and thus *R*'s plan is not subject to the COBRA continuation coverage provisions. However, *R* is in a State that has a State program similar to COBRA. *B* terminates employment with *R* and loses coverage under *R*'s plan.

(ii) In this *Example,* the automatic certificate may be provided not later than the time a notice is required to be furnished under the State program.

Example 4: (i) Individual *C* terminates employment with Employer *S* and receives both a notice of *C*'s rights under COBRA and an automatic certificate. *C* elects COBRA continuation coverage under Employer *S*'s group health plan. After four months of COBRA continuation coverage and the expiration of a 30-day grace period, Employer *S*'s group health plan determines that *C*'s COBRA continuation coverage has ceased due to failure to make a timely payment for continuation coverage.

(ii) In this *Example,* the plan must provide an updated automatic certificate to *C* within a reasonable time after the end of the grace period.

Example 5: (i) Individual *D* is currently covered under the group health plan of Employer *T*. *D* requests a certificate, as permitted under paragraph (a)(2)(iii) of this section. Under the procedure for Employer *T*'s plan, certificates are mailed (by first class mail) 7 business days following receipt of the request. This date reflects the earliest date that the plan, acting in a reasonable and prompt fashion, can provide certificates.

(ii) In this *Example,* the plan's procedure satisfies paragraph (a)(2)(iii) of this section.

(3) *Form and content of certificate*—(i) *Written certificate*—(A) *General.* Except as provided in paragraph (a)(3)(i)(B) of this section, the certificate must be provided in writing (including any form approved by HCFA as a writing).

(B) *Other permissible forms.* No written certificate is required to be provided under this paragraph (a) with respect to a particular event described in paragraphs (a)(2)(ii) and (a)(2)(iii) of this section if all the following conditions are met:

(*1*) An individual is entitled to receive a certificate.

(*2*) The individual requests that the certificate be sent to another plan or issuer instead of to the individual.

(*3*) The plan or issuer that would otherwise receive the certificate agrees to accept the information in this paragraph (a)(3) through means other than a written certificate (for example, by telephone).

(*4*) The receiving plan or issuer receives the information from the sending plan or issuer in such form within the time periods required under paragraph (a)(2) of this section.

(ii) *Required information.* The certificate must include all of the following:

(A) The date the certificate is issued.

(B) The name of the group health plan that provided the coverage described in the certificate.

(C) The name of the participant or dependent with respect to whom the certificate applies, and any other information necessary for the plan providing the coverage specified in the certificate to identify the individual, such as the individual's identification number under the plan and the name of the participant if the certificate is for (or includes) a dependent.

(D) The name, address, and telephone number of the plan administrator or issuer required to provide the certificate.

(E) The telephone number to call for further information regarding the certificate (if different from paragraph (a)(3)(ii)(D)).

(F) Either—

(*1*) A statement that an individual has at least 18 months (for this purpose, 546 days is deemed to be 18 months) of creditable coverage, disregarding days of creditable coverage before a significant break in coverage, or

(*2*) The date any waiting period (and affiliation period, if applicable) began and the date creditable coverage began.

(G) The date creditable coverage ended, unless the certificate indicates that creditable coverage is continuing as of the date of the certificate.

(iii) *Periods of coverage under certificate.* If an automatic certificate is provided under paragraph (a)(2)(ii) of this section, the period that must be included on the certificate is the last period of continuous coverage ending on the date coverage ceased. If an individual requests a certificate under paragraph (a)(2)(iii) of this section, a certificate must be provided for each period of continuous coverage ending within the 24-month period ending on the date of the request (or continuing on the date of the request). A separate certificate may be provided for each such period of continuous coverage.

(iv) *Combining information for families.* A certificate may provide information with respect to both a participant and the participant's dependents if the information is identical for each individual or, if the information is not identical, certificates may be provided on one form if the form provides all the required information for each individual and separately states the information that is not identical.

(v) *Model certificate.* The requirements of paragraph (a)(3)(ii) of this section are satisfied if the plan or issuer provides a certificate in accordance with a model certificate authorized by HCFA.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits described in §146.145. In addition, the information in the certificate regarding coverage is not required to specify categories of benefits described in §146.113(c) (relating to the alternative method of counting creditable coverage). However, if excepted benefits are provided concurrently with other creditable coverage (so that the coverage does not consist solely of excepted benefits), information concerning the benefits may be required to be disclosed under paragraph (b) of this section.

(4) *Procedures*—(i) *Method of delivery.* The certificate is required to be provided to each individual described in paragraph (a)(2) of this section or an entity requesting the certificate on behalf of the individual. The certificate may be provided by first-class mail. If the certificate or certificates are provided to the participant and the participant's spouse at the participant's last known address, then the requirements of this paragraph (a)(4) are satisfied with respect to all individuals residing at that address. If a dependent's last known address is different than the participant's last known address, a separate certificate is required to be provided to the dependent at the dependent's last known address. If separate certificates are being provided by mail to individuals who reside at the same address, separate mailings of each certificate are not required.

(ii) *Procedure for requesting certificates.* A plan or issuer must establish a procedure for individuals to request and receive certificates under paragraph (a)(2)(iii) of this section.

(iii) *Designated recipients.* If an automatic certificate is required to be provided under paragraph (a)(2)(ii) of this section, and the individual entitled to receive the certificate designates another individual or entity to receive the certificate, the plan or issuer responsible for providing the certificate is permitted to provide the certificate to the designated party. If a certificate is required to be provided upon request under paragraph (a)(2)(iii) of this section and the individual entitled to receive the certificate designates another individual or entity to receive the certificate, the plan or issuer responsible for providing the certificate is required to provide the certificate to the designated party.

(5) *Special rules concerning dependent coverage*—(i) *Reasonable efforts*—(A) *General rule.* A plan or issuer is required to use reasonable efforts to determine any information needed for a certificate relating to dependent coverage. In any case in which an automatic certificate is required to be furnished with respect to a dependent under paragraph (a)(2)(ii) of this section, no individual certificate is required to be furnished until the plan or issuer knows (or making reasonable efforts should know) of the dependent's cessation of coverage under the plan.

(B) *Example.* The following example illustrates the requirements of this paragraph (a)(5)(i):

Example: (i) A group health plan covers employees and their dependents. The plan annually requests all employees to provide updated information regarding dependents, including the specific date on which an employee has a new dependent or on which a person ceases to be a dependent of the employee.

(ii) In this *Example,* the plan has satisfied the standard in this paragraph (a)(5)(i) that it make reasonable efforts to determine the cessation of dependents' coverage and the related dependent coverage information.

(ii) *Special rules for demonstrating coverage.* If a certificate furnished by a plan or issuer does not provide the name of any dependent of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (c)(4) of this section for demonstrating dependent status. In addition, an individual may, if necessary, use these procedures to demonstrate that a child was enrolled within 30 days of birth, adoption, or placement for adoption. See §146.111(b), under which such a child would not be subject to a preexisting condition exclusion.

(iii) *Transition rule for dependent coverage through June 30, 1998*—(A) *General.* A group health plan or health insurance issuer that cannot provide the names of dependents (or related coverage information) for purposes of providing a certificate of coverage for a dependent may satisfy the requirements of paragraph (a)(3)(ii)(C) of this section by providing the name of the participant covered by the group health plan or health insurance issuer and specifying that the type of coverage described in the certificate is for dependent coverage (for example, family coverage or employee-plus-spouse coverage).

(B) *Certificates provided on request.* For purposes of certificates provided on the request of, or on behalf of, an individual under paragraph (a)(2)(iii) of this section, a plan or issuer must make reasonable efforts to obtain and provide the names of any dependent covered by the certificate where such

information is requested to be provided. If a certificate does not include the name of any dependent of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (c) of this section for submitting documentation to establish that the creditable coverage in the certificate applies to the dependent.

(C) *Demonstrating a dependent's creditable coverage.* See paragraph (c)(4) of this section for special rules to demonstrate dependent status.

(D) *Duration.* This paragraph (a)(5)(iii) is only effective for certifications provided with respect to events occurring through June 30, 1998.

(6) *Special certification rules*—(i) *Issuers.* Issuers of group and individual health insurance are required to provide certificates of any creditable coverage they provide in the group or individual health insurance market, even if the coverage is provided in connection with an entity or program that is not itself required to provide a certificate because it is not subject to the group market provisions of this part, part 7 of subtitle B of title I of ERISA, or chapter 100 of subtitle K of the Internal Revenue Code. This would include coverage provided in connection with any of the following:

(A) Creditable coverage described in sections 2701 (c)(1)(G) through (c)(1)(J) of the PHS Act (coverage under a State health benefits risk pool, the Federal Employees Health Benefits Program, a public health plan, and a health benefit plan under section 5(e) of the Peace Corps Act).

(B) Coverage subject to section 2721(b)(1)(B) of the PHS Act (requiring certificates by issuers offering health insurance coverage in connection with any group health plan, including a church plan or a governmental plan (including the Federal Employees Health Benefits Program (FEHBP)).

(C) Coverage subject to section 2743 of the PHS Act applicable to health insurance issuers in the individual market. (However, this section does not require a certificate to be provided with respect to short-term, limited duration insurance, which is excluded from the definition of ''individual health insurance coverage'' in 45 CFR 144.103 that is not provided in connection with a group health plan, as described in paragraph (a)(6)(i)(B) of this section.)

(ii) *Other entities.* For special rules requiring that certain other entities, not subject to this part, provide certificates consistent with the rules in this section, see section 2791(a)(3) of the PHS Act applicable to entities described in sections 2701(c)(1)(C), (D), (E), and (F) of the PHS Act (relating to Medicare, Medicaid, CHAMPUS, and Indian Health Service), section 2721(b)(1)(A) of the PHS Act applicable to non-Federal governmental plans generally, section 2721(b)(2)(C)(ii) of the PHS Act applicable to non-Federal governmental plans that elect to be excluded from the requirements of subparts 1 through 3 of part A of title XXVII of the PHS Act, and section 9805(a) of the Internal Revenue Code applicable to group health plans, which includes church plans (as defined in section 414(e) of the Internal Revenue Code).

(b) *Disclosure of coverage to a plan, or issuer, using the alternative method of counting creditable coverage*—(1) *General.* If an individual enrolls in a group health plan with respect to which the plan, or issuer, uses the alternative method of counting creditable coverage described in section 2701(c)(3)(B) of the PHS Act and §146.113(c), the individual provides a certificate of coverage under paragraph (a) of this section, and the plan or issuer in which the individual enrolls so requests, the entity that issued the certificate (the ''prior entity'') is required to disclose promptly to a requesting plan or issuer (the ''requesting entity'') the information set forth in paragraph (b)(2) of this section.

(2) *Information to be disclosed.* The prior entity is required to identify to the requesting entity the categories of benefits with respect to which the requesting entity is using the alternative method of counting creditable coverage, and the requesting entity may identify specific information that the requesting entity reasonably needs in order to determine the individual's creditable coverage with respect to any such category. The prior entity is required to disclose promptly to the requesting entity the creditable coverage information so requested.

(3) *Charge for providing information.* The prior entity furnishing the information under paragraph (b) of this section may charge the requesting entity for the reasonable cost of disclosing such information.

(c) *Ability of an individual to demonstrate creditable coverage and waiting period information*—(1) *General.* The rules in this paragraph (c) implement section 2701(c)(4) of the PHS Act, which permits individuals to establish creditable coverage through means other than certificates, and section 2701(e)(3) of the PHS Act, which requires the Secretary to establish rules designed to prevent an individual's subsequent coverage under a group health plan or health insurance coverage from being adversely affected by an entity's failure to provide a certificate with respect to that individual. If the accuracy of a certificate is contested or a certificate is unavailable when needed by the individual, the individual has the right to demonstrate creditable coverage (and waiting or affiliation periods) through the presentation of documents or other means. For example, the individual may make such a demonstration when—

(i) An entity has failed to provide a certificate within the required time period;

(ii) The individual has creditable coverage but an entity may not be required to provide a certificate of the coverage under paragraph (a) of this section;

(iii) The coverage is for a period before July 1, 1996;

(iv) The individual has an urgent medical condition that necessitates a determination before the individual can deliver a certificate to the plan; or

(v) The individual lost a certificate that the individual had previously received and is unable to obtain another certificate.

(2)*Evidence of creditable coverage*—(i) *Consideration of evidence.* A plan or issuer is required to take into account all information that it obtains or that is presented on behalf of an individual to make a determination, based on the relevant facts and circumstances, whether an individual has creditable coverage and is entitled to offset all or a portion of any preexisting condition exclusion period. A plan or issuer shall treat the individual as having furnished a certificate under paragraph (a) of this section if the individual attests to the period of creditable coverage, the individual also presents relevant corroborating evidence of some creditable coverage during the period, and the individual cooperates with the plan's or issuer's efforts to verify the individual's coverage. For this purpose, cooperation includes providing (upon the plan's or issuer's request) a written authorization for the plan or issuer to request a certificate on behalf of the individual, and cooperating in efforts to determine the validity of the corroborating evidence and the dates of creditable coverage. While a plan or issuer may refuse to credit coverage where the individual fails to cooperate with the plan's or issuer's efforts to verify coverage, the plan or issuer may not consider an individual's inability to obtain a certificate to be evidence of the absence of creditable coverage.

(ii) *Documents.* Documents that may establish creditable coverage (and waiting periods or affiliation periods) in the absence of a certificate include explanations of benefit claims (EOBs) or other correspondence from a plan or issuer indicating coverage, pay stubs showing a payroll deduction for health coverage, a health insurance identification card, a certificate of coverage under a group health policy, records from medical care providers indicating health coverage, third party statements verifying periods of coverage, and any other relevant documents that evidence periods of health coverage.

(iii) *Other evidence.* Creditable coverage (and waiting period or affiliation period information) may also be established through means other than documentation, such as by a telephone call from the plan or provider to a third party verifying creditable coverage.

(iv) *Example.* The following example illustrates the requirements of this paragraph (c)(2):

Example: (i) Individual *F* terminates employment with Employer *W* and, a month later, is hired by Employer *X*. Employer *X*'s group health plan imposes a preexisting condition exclusion of 12 months on new enrollees under the plan and uses the standard method of determining creditable coverage.

F fails to receive a certificate of prior coverage from the self-insured group health plan maintained by *F*'s prior employer, Employer *W*, and requests a certificate. However, *F* (and Employer *X*'s plan, on *F*'s behalf) is unable to obtain a certificate from Employer *W*'s plan. *F* attests that, to the best of *F*'s knowledge, *F* had at least 12 months of continuous coverage under Employer *W*'s plan, and that the coverage ended no earlier than *F*'s termination of employment from Employer *W*. In addition, *F* presents evidence of coverage, such as an explanation of benefits for a claim that was made during the relevant period.

(ii) In this *Example,* based solely on these facts, *F* has demonstrated creditable coverage for the 12 months of coverage under Employer *W*'s plan in the same manner as if *F* had presented a written certificate of creditable coverage.

(3) *Demonstrating categories of creditable coverage.* Procedures similar to those described in this paragraph (c) apply in order to determine an individual's creditable coverage with respect to any category under paragraph (b) of this section (relating to determining creditable coverage under the alternative method).

(4) *Demonstrating dependent status.* If, in the course of providing evidence (including a certificate) of creditable coverage, an individual is required to demonstrate dependent status, the group health plan or issuer is required to treat the individual as having furnished a certificate showing the dependent status if the individual attests to such dependency and the period of such status and the individual cooperates with the plan's or issuer's efforts to verify the dependent status.

(d) *Determination and notification of creditable coverage*—(1) *Reasonable time period.* In the event that a group health plan or health insurance issuer offering group health insurance coverage receives information in this section under paragraph (a) (certifications), paragraph (b) (disclosure of information relating to the alternative method), or paragraph (c) (other evidence of creditable coverage), the entity is required, within a reasonable time period following receipt of the information, to make a determination regarding the individual's period of creditable coverage and notify the individual of the determination in accordance with paragraph (d)(2) of this section. Whether a determination and notification regarding an individual's creditable coverage is made within a reasonable time period is determined based on the relevant facts and circumstances. Relevant facts and circumstances include whether a plan's application of a preexisting condition exclusion would prevent an individual from having access to urgent medical services.

(2) *Notification to individual of period of preexisting condition exclusion.* A plan or issuer seeking to impose a preexisting condition exclusion is required to disclose to the individual, in writing, its determination of any preexisting condition exclusion period that applies to the individual, and the basis for such determination, including the source and substance of any information on which the plan or issuer relied. In addition, the plan or issuer is required to provide the individual with a written explanation of any appeal procedures established by the plan or issuer, and with a reasonable opportunity to submit additional evidence of creditable coverage. However, nothing in this paragraph (d) or paragraph (c) of this section prevents a plan or issuer from modifying an initial determination of creditable coverage if it determines that the individual did not have the claimed creditable coverage, provided that—

(i) A notice of the reconsideration is provided to the individual; and

(ii) Until the final determination is made, the plan or issuer, for purposes of approving access to medical services (such as a pre-surgery authorization), acts in a manner consistent with the initial determination.

(3) *Examples.* The following examples illustrate this paragraph (d):

Example 1: (i) Individual *F* terminates employment with Employer *W* and, a month later, is hired by Employer *X*. *Example 1:* Individual *G* is hired by Employer *Y*. Employer *Y*'s group health plan imposes a preexisting condition exclusion for 12 months with respect to new enrollees and uses the standard method of determining creditable coverage. Employer *Y*'s plan determines that *G* is subject to a 4-month preexisting condition exclusion, based on a certificate of creditable coverage that is provided by *G* to Employer *Y*'s plan indicating 8 months of coverage under *G*'s prior group health plan.

(ii) In this *Example,* Employer *Y*'s plan must notify *G* within a reasonable period of time following receipt of the certificate that *G* is subject to a 4-month preexisting condition exclusion beginning on *G*'s enrollment date in *Y*'s plan.

Example 2: (i) Same facts as in *Example 1,* except that Employer *Y*'s plan determines that *G* has 14 months of creditable coverage based on *G*'s certificate indicating 14 months of creditable coverage under *G*'s prior plan.

(ii) In this *Example,* Employer *Y*'s plan is not required to notify *G* that *G* will not be subject to a preexisting condition exclusion.

Example 3: (i) Individual *H* is hired by Employer *Z*. Employer *Z*'s group health plan imposes a preexisting condition exclusion for 12 months with respect to new enrollees and uses the standard method of determining creditable coverage. *H* develops an urgent health condition before receiving a certificate of prior coverage. *H* attests to the period of prior coverage, presents corroborating documentation of the coverage period, and authorizes the plan to request a certificate on *H*'s behalf.

(ii) In this *Example,* Employer *Z*'s plan must review the evidence presented by *H*. In addition, the plan must make a determination and notify *H* regarding any preexisting condition exclusion period that applies to *H* (and the basis of such determination) within a reasonable time period following receipt of the evidence that is consistent with the urgency of *H*'s health condition, (This determination may be modified as permitted under paragraph (d)(2)).

(Approved by the Office of Management and Budget under control number 0938–0702.)

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§ 146.117 Special enrollment periods.

(a) *Special enrollment for certain individuals who lose coverage*—(1) *General.* A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, is required to permit employees and dependents described in this section in paragraph (a)(2), (a)(3), or (a)(4) to enroll for coverage under the terms of the plan if the conditions in paragraph (a)(5) are satisfied and the enrollment is requested within the period described in paragraph (a)(6). The enrollment is effective at the time described in paragraph (a)(7). The special enrollment rights under this paragraph (a) apply without regard to the dates on which an individual would otherwise be able to enroll under the plan.

(2) *Special enrollment of an employee only.* An employee is described in this paragraph (a)(2) if the employee is eligible, but not enrolled, for coverage under the terms of the plan and, when enrollment was previously offered to the employee under the plan and was declined by the employee, the employee was covered under another group health plan or had other health insurance coverage.

(3) *Special enrollment of dependents only.* A dependent is described in this paragraph (a)(3) if the dependent is a dependent of an employee participating in the plan, the dependent is eligible, but not enrolled, for coverage under the terms of the plan, and, when enrollment was previously offered under the plan and was declined, the dependent was covered under another group health plan or had other health insurance coverage.

(4) *Special enrollment of both employee and dependent.* An employee and any dependent of the employee are described in this paragraph (a)(4) if they are eligible, but not enrolled, for coverage under the terms of the plan and, when enrollment was previously offered to the employee or dependent under the plan and was declined, the employee or dependent was covered under another group health plan or had other health insurance coverage.

(5) *Conditions for special enrollment.* An employee or dependent is eligible to enroll during a special enrollment period if each of the following applicable conditions is met:

(i) When the employee declined enrollment for the employee or the dependent, the employee stated in writing that coverage under another group health plan or other health insurance coverage was the reason for declining enrollment. This paragraph (a)(5)(i) applies only if—

(A) The plan required such a statement when the employee declined enrollment; and

(B) The employee is provided with notice of the requirement to provide the statement in paragraph (a)(5)(i) (and the consequences of the employee's failure to provide the statement)

at the time the employee declined enrollment.

(ii)(A) When the employee declined enrollment for the employee or dependent under the plan, the employee or dependent had COBRA continuation coverage under another plan and COBRA continuation coverage under that other plan has since been exhausted; or

(B) If the other coverage that applied to the employee or dependent when enrollment was declined was not under a COBRA continuation provision, either the other coverage has been terminated as a result of loss of eligibility for the coverage or employer contributions towards the other coverage have been terminated. For this purpose, loss of eligibility for coverage includes a loss of coverage as a result of legal separation, divorce, death, termination of employment, reduction in the number of hours of employment, and any loss of eligibility after a period that is measured by reference to any of the foregoing. Thus, for example, if an employee's coverage ceases following a termination of employment and the employee is eligible for but fails to elect COBRA continuation coverage, this is treated as a loss of eligibility under this paragraph (a)(5)(ii)(B). However, loss of eligibility does not include a loss due to failure of the individual or the participant to pay premiums on a timely basis or termination of coverage for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). In addition, for purposes of this paragraph (a)(5)(ii)(B), employer contributions include contributions by any current or former employer (of the individual or another person) that was contributing to coverage for the individual.

(6) *Length of special enrollment period.* The employee is required to request enrollment (for the employee or the employee's dependent, as described in this section in paragraph (a)(2), paragraph (a)(3), or paragraph (a)(4)) not later than 30 days after the exhaustion of the other coverage described in paragraph (a)(5)(ii)(A) or termination of the other coverage as a result of the loss of eligibility for the other coverage for items described in paragraph (a)(5)(ii)(B) or following the termination of employer contributions toward that other coverage. The plan may impose the same requirements that apply to employees who are otherwise eligible under the plan to immediately request enrollment for coverage (for example, that the request be made in writing).

(7) *Effective date of enrollment.* Enrollment is effective not later than the first day of the first calendar month beginning after the date the completed request for enrollment is received.

(b) *Special enrollment with respect to certain dependent beneficiaries*—(1) *General.* A group health plan that makes coverage available with respect to dependents of a participant is required to provide a special enrollment period to permit individuals described in this section in paragraph (b)(2), (b)(3), (b)(4), (b)(5), or (b)(6) to be enrolled for coverage under the terms of the plan if the enrollment is requested within the time period described in paragraph (b)(7). The enrollment is effective at the time described in paragraph (b)(8). The special enrollment rights under this paragraph (b) apply without regard to the dates on which an individual would otherwise be able to enroll under the plan.

(2) *Special enrollment of an employee who is eligible but not enrolled.* An individual is described in this paragraph (b)(2) if the individual is an employee who is eligible, but not enrolled, for coverage under the terms of the plan, the individual would be a participant but for a prior election by the individual not to enroll in the plan during a previous enrollment period, and a person becomes a dependent of the individual through marriage, birth, or adoption or placement for adoption.

(3) *Special enrollment of a spouse of a participant.* An individual is described in this paragraph (b)(3) if either—

(i) The individual becomes the spouse of a participant; or

(ii) The individual is a spouse of the participant and a child becomes a dependent of the participant through birth, adoption, or placement for adoption.

(4) *Special enrollment of an employee who is eligible, but not enrolled, for coverage under the terms of the spouse of such employee.* An employee who is eligible, but not enrolled, in the plan, and

an individual who is a dependent of such employee, are described in this paragraph (b)(4) if the employee would be a participant but for a prior election by the employee not to enroll in the plan during a previous enrollment period, and either—

(i) The employee and the individual become married; or

(ii) The employee and individual are married and a child becomes a dependent of the employee through birth, adoption or placement for adoption.

(5) *Special enrollment of a dependent of a participant.* An individual is described in this paragraph (b)(5) if the individual is a dependent of a participant and the individual becomes a dependent of such participant through marriage, birth, or adoption or placement for adoption.

(6) *Special enrollment of an employee who is eligible but not enrolled and a new dependent.* An employee who is eligible, but not enrolled, for coverage under the terms of the plan, and an individual who is a dependent of the employee, are described in this paragraph (b)(6) if the employee would be a participant but for a prior election by the employee not to enroll in the plan during a previous enrollment period, and the dependent becomes a dependent of the employee through marriage, birth, or adoption or placement for adoption.

(7) *Length of special enrollment period.* The special enrollment period under paragraph (b)(1) of this section is a period of not less than 30 days and begins on the date of the marriage, birth, or adoption or placement for adoption (except that such period does not begin earlier than the date the plan makes dependent coverage generally available).

(8) *Effective date of enrollment.* Enrollment is effective—

(i) In the case of marriage, not later than the first day of the first calendar month beginning after the date the completed request for enrollment is received by the plan;

(ii) In the case of a dependent's birth, the date of such birth; and

(iii) In the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

(9) *Example.* The following example illustrates the requirements of this paragraph (b):

Example: (i) Employee *A* is hired on September 3, 1998 by Employer *X*, which has a group health plan in which *A* can elect to enroll either for employee-only coverage, for employee-plus-spouse coverage, or for family coverage, effective on the first day of any calendar quarter thereafter. *A* is married and has no children. *A* does not elect to join Employer *X*'s plan (for employee-only coverage, employee-plus-spouse coverage, or family coverage) on October 1, 1998 or January 1, 1999. On February 15, 1999, a child is placed for adoption with *A* and *A*'s spouse.

(ii) In this *Example*, the conditions for special enrollment of an employee with a new dependent under paragraph (b)(2) are satisfied, the conditions for special enrollment of an employee and a spouse with a new dependent under paragraph (b)(4) are satisfied, and the conditions for special enrollment of an employee and a new dependent under paragraph (b)(6) are satisfied. Accordingly, Employer *X*'s plan will satisfy this paragraph (b) if and only if it allows *A* to elect, by filing the required forms by March 16, 1999, to enroll in Employer *X*'s plan either with employee-only coverage, with employee-plus-spouse coverage, or with family coverage, effective as of February 15, 1999.

(c) *Notice of enrollment rights.* On or before the time an employee is offered the opportunity to enroll in a group health plan, the plan is required to provide the employee with a description of the plan's special enrollment rules under this section. For this purpose, the plan may use the following model description of the special enrollment rules under this section:

If you are declining enrollment for yourself or your dependents (including your spouse) because of other health insurance coverage, you may in the future be able to enroll yourself or your dependents in this plan, provided that you request enrollment within 30 days after your other coverage ends. In addition, if you have a new dependent as a result of marriage, birth, adoption or placement for adoption, you may be able to enroll yourself and your dependents, provided that you request enrollment within 30 days after the marriage, birth, adoption, or placement for adoption.

(d) *Special enrollment date definition.* (1) *General rule.* A special enrollment date for an individual means any date

in paragraph (a)(7) or paragraph (b)(8) of this section on which the individual has a right to have enrollment in a group health plan become effective under this section.

(2) *Examples.* The following examples illustrate the requirements of this paragraph (d):

Example 1: (i) Employer *Y* maintains a group health plan that allows employees to enroll in the plan either (a) effective on the first day of employment by an election filed within three days thereafter, (b) effective on any subsequent January 1 by an election made during the preceding months of November or December, or (c) effective as of any special enrollment date described in this section. Employee *B* is hired by Employer *Y* on March 15, 1998 and does not elect to enroll in Employer *Y*'s plan until January 31, 1999 when *B* loses coverage under another plan. *B* elects to enroll in Employer *Y*'s plan effective on February 1, 1999 by filing the completed request form by January 31, 1999, in accordance with the special rule set forth in paragraph (a).

(ii) In this *Example, B* has enrolled on a special enrollment date because the enrollment is effective at a date described in paragraph (a)(7).

Example 2: (i) Same facts as *Example 1,* except that *B*'s loss of coverage under the other plan occurs on December 31, 1998 and *B* elects to enroll in Employer *Y*'s plan effective on January 1, 1999 by filing the completed request form by December 31, 1998, in accordance with the special rule set forth in paragraph (a).

(ii) In this *Example, B* has enrolled on a special enrollment date because the enrollment is effective at a date described in paragraph (a)(7) (even though this date is also a regular enrollment date under the plan).

(Approved by the Office of Management and Budget under control number 0938–0702.)

[62 FR 16958, Apr. 8, 1997; 62 FR 31694, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 146.119 HMO affiliation period as alternative to preexisting condition exclusion.

(a) *General.* A group health plan offering health insurance coverage through an HMO, or an HMO that offers health insurance coverage in connection with a group health plan, may impose an affiliation period only if each of the requirements in paragraph (b) of this section is satisfied.

(b) *Requirements for affiliation period.* (1) No preexisting condition exclusion is imposed with respect to any coverage offered by the HMO in connection with the particular group health plan.

(2) No premium is charged to a participant or beneficiary for the affiliation period.

(3) The affiliation period for the HMO coverage is applied uniformly without regard to any health status-related factors.

(4) The affiliation period does not exceed 2 months (or 3 months in the case of a late enrollee).

(5) The affiliation period begins on the enrollment date.

(6) The affiliation period for enrollment in the HMO under a plan runs concurrently with any waiting period.

(c) *Alternatives to affiliation period.* An HMO may use alternative methods in lieu of an affiliation period to address adverse selection, as approved by the State insurance commissioner or other official designated to regulate HMOs. Nothing in this section requires a State to receive proposals for or approve alternatives to affiliation periods.

§ 146.121 Prohibiting discrimination against participants and beneficiaries based on a health status-related factor.

(a) *In eligibility to enroll*—(1) *General.* Subject to paragraph (a)(2) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

(i) Health status.

(ii) Medical condition (including both physical and mental illnesses), as defined in 45 CFR 144.103.

(iii) Claims experience.

(iv) Receipt of health care.

(v) Medical history.

(vi) Genetic information, as defined in 45 CFR 144.103.

(vii) Evidence of insurability (including conditions arising out of acts of domestic violence).

(viii) Disability.

(2) *No application to benefits or exclusions.* To the extent consistent with section 2701 of the Act and § 146.111,

paragraph (a)(1) of this section shall not be construed—

(i) To require a group health plan, or a health insurance issuer offering group health insurance coverage, to provide particular benefits other than those provided under the terms of such plan or coverage; or

(ii) To prevent such a plan or issuer from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

(3) *Construction.* For purposes of paragraph (a)(1) of this section, rules for eligibility to enroll include rules defining any applicable waiting (or affiliation) periods for such enrollment and rules relating to late and special enrollment.

4. *Example.* The following example illustrates the requirements of this paragraph (a):

Example: (i) An employer sponsors a group health plan that is available to all employees who enroll within the first 30 days of their employment. However, individuals who do not enroll in the first 30 days cannot enroll later unless they pass a physical examination.

(ii) In this *Example,* the plan discriminates on the basis of one or more health status-related factors.

(b) *In premiums or contributions*—(1) *General.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require an individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual enrolled in the plan based on any health status-related factor, in relation to the individual or a dependent of the individual.

(2) *Construction.* Nothing in paragraph (b)(1) of this section can be construed—

(i) To restrict the amount that an employer may be charged by an issuer for coverage under a group health plan; or

(ii) To prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to a bona fide wellness program. For purposes of this section, a bona fide wellness program is a program of health promotion and disease prevention.

(3) *Example:* The following example illustrates the requirements of this paragraph (b):

Example. (i) Plan *X* offers a premium discount to participants who adhere to a cholesterol-reduction wellness program. Enrollees are expected to keep a diary of their food intake over 6 weeks. They periodically submit the diary to the plan physician who responds with suggested diet modifications. Enrollees are to modify their diets in accordance with the physician's recommendations. At the end of the 6 weeks, enrollees are given a cholesterol test and those who achieve a count under 200 receive a premium discount.

(ii) In this *Example,* because enrollees who otherwise comply with the program may be unable to achieve a cholesterol count under 200 due to a health status-related factor, this is not a bona fide wellness program and such discounts would discriminate impermissibly based on one or more health status-related factors. However, if, instead, individuals covered by the plan were entitled to receive the discount for complying with the diary and dietary requirements and were not required to pass a cholesterol test, the program would be a bona fide wellness program.

[62 FR 16958, Apr. 8, 1997; 62 FR 31694, June 10, 1997]

§ 146.125 Effective dates.

(a) *General effective dates*—(1) *Non-collectively-bargained plans.* Except as otherwise provided in this section, part A of title XXVII of the PHS Act and this part apply with respect to group health plans, including health insurance issuers offering health insurance coverage in connection with group health plans, for plan years beginning after June 30, 1997.

(2) *Collectively bargained plans.* Except as otherwise provided in this section (other than paragraph (a)(1)), in the case of a group health plan maintained under one or more collective bargaining agreements between employee representatives and one or more employers ratified before August 21, 1996, part A of title XXVII of the PHS Act and this part do not apply to plan years beginning before the later of July 1, 1997,

or the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after August 21, 1996). For these purposes, any plan amendment made under a collective bargaining agreement relating to the plan, that amends the plan solely to conform to any requirement of such part, is not treated as a termination of the collective bargaining agreement.

(3) *Preexisting condition exclusion periods for current employees.* (i) *General rule.* Any preexisting condition exclusion period permitted under § 146.111 is measured from the individual's enrollment date in the plan. This exclusion period, as limited under § 146.111, may be completed before the effective date of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for his or her plan. Therefore, on the date the individual's plan becomes subject to part A of title XXVII of the PHS Act, no preexisting condition exclusion may be imposed with respect to an individual beyond the limitation in § 146.111. For an individual who has not completed the permitted exclusion period under HIPAA, upon the effective date for his or her plan, the individual may use creditable coverage that the person had as of the enrollment date to reduce the remaining preexisting condition exclusion period applicable to the individual.

(ii) *Examples.* The following examples illustrate the requirements of this paragraph (a)(3):

Example 1: (i) Individual *A* has been working for Employer *X* and has been covered under Employer *X*'s plan since March 1, 1997. Under Employer *X*'s plan, as in effect before January 1, 1998, there is no coverage for any preexisting condition. Employer *X*'s plan year begins on January 1, 1998. *A*'s enrollment date in the plan is March 1, 1997, and *A* has no creditable coverage before this date.

(ii) In this *Example,* Employer *X* may continue to impose the preexisting condition exclusion under the plan through February 28, 1998 (the end of the 12-month period using anniversary dates).

Example 2: (i) Same facts as in *Example 1,* except that *A*'s enrollment date was August 1, 1996, instead of March 1, 1997.

(ii) In this *Example,* on January 1, 1998, Employer *X*'s plan may no longer exclude treatment for any preexisting condition that *A* may have; however, because Employer *X*'s plan is not subject to HIPAA until January 1, 1998, *A* is not entitled to claim reimbursement for expenses under the plan for treatments for any preexisting condition received before January 1, 1998.

(b) *Effective date for certification requirement*—(1) *General.* Subject to the transitional rule in § 146.115(a)(5)(iii), the certification rules of § 146.115 apply to events occurring on or after July 1, 1996.

(2) *Period covered by certificate.* A certificate is not required to reflect coverage before July 1, 1996.

(3) *No certificate before June 1, 1997.* Notwithstanding any other provision of this part, in no case is a certificate required to be provided before June 1, 1997.

(c) *Limitation on actions.* No enforcement action is to be taken, under, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by part A of title XXVII of the PHS Act before January 1, 1998, if the plan or issuer has sought to comply in good faith with such requirements. Compliance with this part is deemed to be good faith compliance with the requirements of part A of title XXVII of the PHS Act.

(d) *Transition rules for counting creditable coverage.* An individual who seeks to establish creditable coverage for periods before July 1, 1996 is entitled to establish such coverage through the presentation of documents or other means in accordance with the provisions of § 146.115(c). For coverage relating to an event occurring before July 1, 1996, a group health plan and a health insurance issuer are not subject to any penalty or enforcement action with respect to the plan's or issuer's counting (or not counting) such coverage if the plan or issuer has sought to comply in good faith with the applicable requirements under § 146.115(c).

(e) *Transition rules for certification of creditable coverage*—(1) *Certificates only upon request.* For events occurring on or after July 1, 1996 but before October 1, 1996, a certificate is required to be provided only upon a written request by or on behalf of the individual to whom the certificate applies.

(2) *Certificates before June 1, 1997.* For events occurring on or after October 1,

1996 and before June 1, 1997, a certificate must be furnished no later than June 1, 1997, or any later date permitted under §146.115(a)(2) (ii) and (iii).

(3) *Optional notice*—(i) *General.* This paragraph (e)(3) applies with respect to events described in §146.115(a)(2)(ii), that occur on or after October 1, 1996 but before June 1, 1997. A group health plan or health insurance issuer offering group health coverage is deemed to satisfy §§146.115 (a)(2) and (a)(3) if a notice is provided in accordance with the provisions of paragraphs (e)(3)(i) through (e)(3)(iv) of this section.

(ii) *Time of notice.* The notice must be provided no later than June 1, 1997.

(iii) *Form and content of notice.* A notice provided under this paragraph (e)(3) must be in writing and must include information substantially similar to the information included in a model notice authorized by HCFA. Copies of the model notice are available at the following website—www.hcfa.gov (or call (410) 786–1565).

(iv) *Providing certificate after request.* If an individual requests a certificate following receipt of the notice, the certificate must be provided at the time of the request as set forth in §146.115(a)(2)(iii).

(v) *Other certification rules apply.* The rules set forth in §146.115(a)(4)(i) (method of delivery) and (a)(1) (entities required to provide a certificate) apply with respect to the provision of the notice.

[62 FR 16958, Apr. 8, 1997; 62 FR 31694, June 10, 1997]

Subpart C [Reserved]

Subpart D—Preemption and Special Rules

§146.143 Preemption; State flexibility; construction.

(a) *Continued applicability of State law with respect to health insurance issuers.* Subject to paragraph (b) of this section and except as provided in paragraph (c) of this section, part A of title XXVII of the PHS Act is not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of part A of title XXVII of the PHS Act.

(b) *Continued preemption with respect to group health plans.* Nothing in part A of title XXVII of the PHS Act affects or modifies the provisions of section 514 of ERISA with respect to group health plans.

(c) *Special rules*—(1) *General.* Subject to paragraph (c)(2) of this section, the provisions of part A of title XXVII of the PHS Act relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 2701 of the PHS Act, which differs from the standards or requirements specified in such section.

(2) *Exceptions.* Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

(i) Shortens the period of time from the ''6-month period'' described in section 2701(a)(1) of the PHS Act and §146.111(a)(1)(i) (for purposes of identifying a preexisting condition);

(ii) Shortens the period of time from the ''12 months'' and ''18 months'' described in section 2701(a)(2) of the PHS Act and §146.111(a)(1)(ii) (for purposes of applying a preexisting condition exclusion period);

(iii) Provides for a greater number of days than the ''63-day period'' described in sections 2701 (c)(2)(A) and (d)(4)(A) of the PHS Act and §§146.111(a)(1)(iii) and 146.113 (for purposes of applying the break in coverage rules);

(iv) Provides for a greater number of days than the ''30-day period'' described in sections 2701 (b)(2) and (d)(1) of the PHS Act and §146.111(b) (for purposes of the enrollment period and preexisting condition exclusion periods for certain newborns and children that are adopted or placed for adoption);

(v) Prohibits the imposition of any preexisting condition exclusion in cases not described in section 2701(d) of the PHS Act or expands the exceptions described in that section;

(vi) Requires special enrollment periods in addition to those required under section 2701(f) of the PHS Act; or

(vii) Reduces the maximum period permitted in an affiliation period under section 701(g)(1)(B).

(d) *Definitions*—(1) *State law.* For purposes of this section the term ''State law'' includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia is treated as a State law rather than a law of the United States.

(2) *State.* For purposes of this section the term ''State'' includes a State, the Northern Mariana Islands, any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

§ 146.145 Special rules relating to group health plans.

(a) *General exception for certain small group health plans.* The requirements of this part do not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of the plan year, the plan has fewer than 2 participants who are current employees.

(b) *Excepted benefits*—(1) *General.* The requirements of subpart B of this part do not apply to any group health plan (or any group health insurance coverage offered in connection with a group health plan) in relation to its provision of the benefits described in paragraph (b)(2), (3), (4), or (5) of this section (or any combination of these benefits).

(2) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances:

(i) Coverage only for accident (including accidental death and dismemberment).

(ii) Disability income insurance.

(iii) Liability insurance, including general liability insurance and automobile liability insurance.

(iv) Coverage issued as a supplement to liability insurance.

(v) Workers' compensation or similar insurance.

(vi) Automobile medical payment insurance.

(vii) Credit-only insurance (for example, mortgage insurance).

(viii) Coverage for on-site medical clinics.

(3) *Limited excepted benefits*—(1) *General.* Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of the plan, as defined in paragraph (b)(3)(ii) of this section.

(ii) *Integral.* For purposes of paragraph (b)(3)(i) of this section, benefits are deemed to be an integral part of a plan unless a participant has the right to elect not to receive coverage for the benefits and, if the participant elects to receive coverage for the benefits, the participant pays an additional premium or contribution for that coverage.

(iii) *Limited scope.* Limited scope dental or vision benefits are dental or vision benefits that are sold under a separate policy or rider and that are limited in scope to a narrow range or type of benefits that are generally excluded from hospital/medical/surgical benefits packages.

(iv) *Long-term care.* Long-term care benefits are benefits that are either—

(A) Subject to State long-term care insurance laws;

(B) For qualified long-term care insurance services, as defined in section 7702B(c)(1) of the Internal Revenue Code, or provided under a qualified long-term care insurance contract, as defined in section 7702B(b) of the Internal Revenue Code; or

(C) based on cognitive impairment or a loss of functional capacity that is expected to be chronic.

(4) *Noncoordinated benefits*—(i) *Excepted benefits that are not coordinated.* Coverage for only a specified disease or illness (for example, cancer-only policies) or hospital indemnity or other fixed dollar indemnity insurance (for example, $100/day) is excepted only if it

meets each of the conditions specified in paragraph (b)(4)(ii) of this section.

(ii) *Conditions.* Benefits are described in paragraph (b)(4)(i) of this section only if—

(A) The benefits are provided under a separate policy, certificate, or contract of insurance;

(B) There is no coordination between the provision of the benefits and an exclusion of benefits under any group health plan maintained by the same plan sponsor; and

(C) The benefits are paid with respect to an event without regard to whether benefits are provided with respect to the event under any group health plan maintained by the same plan sponsor.

(5) *Supplemental benefits.* The following benefits are excepted only if they are provided under a separate policy, certificate, or contract of insurance:

(i) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act; also known as Medigap or MedSupp insurance);

(ii) Coverage supplemental to the coverage provided under Chapter 55, Title 10 of the United States Code (also known as CHAMPUS supplemental programs); and

(iii) Similar supplemental coverage provided to coverage under a group health plan.

[62 FR 16958, Apr. 8, 1997; 62 FR 31670, June 10, 1997]

Subpart E—Provisions Applicable to Only Health Insurance Issuers

§ 146.150 Guaranteed availability of coverage for employers in the small group market.

(a) *Issuance of coverage in the small group market.* Subject to paragraphs (c) through (f) of this section, each health insurance issuer that offers health insurance coverage in the small group market in a State must—

(1) Offer, to any small employer in the State, all products that are approved for sale in the small group market and that the issuer is actively marketing, and must accept any employer that applies for any of those products; and

(2) Accept for enrollment under the coverage every eligible individual (as defined in paragraph (b) of this section) who applies for enrollment during the period in which the individual first becomes eligible to enroll under the terms of the group health plan, or during a special enrollment period, and may not impose any restriction on an eligible individual's being a participant or beneficiary, which is inconsistent with the nondiscrimination provisions of § 146.121.

(b) *Eligible individual defined.* For purposes of this section, the term ''eligible individual'' means an individual who is eligible—

(1) To enroll in group health insurance coverage offered to a group health plan maintained by a small employer, in accordance with the terms of the group health plan;

(2) For coverage under the rules of the health insurance issuer which are uniformly applicable in the State to small employers in the small group market; and

(3) For coverage in accordance with all applicable State laws governing the issuer and the small group market.

(c) *Special rules for network plans.* (1) In the case of a health insurance issuer that offers health insurance coverage in the small group market through a network plan, the issuer may—

(i) Limit the employers that may apply for the coverage to those with eligible individuals who live, work, or reside in the service area for the network plan; and

(ii) Within the service area of the plan, deny coverage to employers if the issuer has demonstrated to the applicable State authority (if required by the State authority) that—

(A) It will not have the capacity to deliver services adequately to enrollees of any additional groups because of its obligations to existing group contract holders and enrollees; and

(B) It is applying this paragraph (c)(1) uniformly to all employers without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents.

(2) An issuer that denies health insurance coverage to an employer in any service area, in accordance with paragraph (c)(1)(ii) of this section, may

not offer coverage in the small group market within the service area to any employer for a period of 180 days after the date the coverage is denied. This paragraph (c)(2) does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(3) Coverage offered within a service area after the 180-day period specified in paragraph (c)(2) of this section is subject to the requirements of this section.

(d) *Application of financial capacity limits.* (1) A health insurance issuer may deny health insurance coverage in the small group market if the issuer has demonstrated to the applicable State authority (if required by the State authority) that it—

(i) Does not have the financial reserves necessary to underwrite additional coverage; and

(ii) Is applying this paragraph (d)(1) uniformly to all employers in the small group market in the State consistent with applicable State law and without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents.

(2) An issuer that denies group health insurance coverage to any small employer in a State in accordance with paragraph (d)(1) of this section may not offer coverage in connection with group health plans in the small group market in the State for a period of 180 days after the later of the date—

(i) The coverage is denied; or

(ii) The issuer demonstrates to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage.

(3) Paragraph (d)(2) of this section does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(4) Coverage offered after the 180-day period specified in paragraph (d)(2) of this section is subject to the requirements of this section.

(5) An applicable State authority may provide for the application of this paragraph (d) on a service-area-specific basis.

(e) *Exception to requirement for failure to meet certain minimum participation or contribution rules.*

(1) Paragraph (a) of this section does not preclude a health insurance issuer from establishing employer contribution rules or group participation rules for the offering of health insurance coverage in connection with a group health plan in the small group market, as allowed under applicable State law.

(2) For purposes of paragraph (e)(1) of this section—

(i) The term ''employer contribution rule'' means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries; and

(ii) The term ''group participation rule'' means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

(f) *Exception for coverage offered only to bona fide association members.* Paragraph (a) of this section does not apply to health insurance coverage offered by a health insurance issuer if that coverage is made available in the small group market only through one or more bona fide associations (as defined in 45 CFR 144.103).

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[62 FR 16958, Apr. 8, 1997; 62 FR 31694, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 146.152 Guaranteed renewability of coverage for employers in the group market.

(a) *General rule.* Subject to paragraphs (b) through (d) of this section, a health insurance issuer offering health insurance coverage in the small or large group market is required to renew or continue in force the coverage at the option of the plan sponsor.

(b) *Exceptions.* An issuer may nonrenew or discontinue group health insurance coverage offered in the small or large group market based only on one or more of the following:

(1) *Nonpayment of premiums.* The plan sponsor has failed to pay premiums or contributions in accordance with the

terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The plan sponsor has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact in connection with the coverage.

(3) *Violation of participation or contribution rules.* The plan sponsor has failed to comply with a material plan provision relating to any employer contribution or group participation rules permitted under § 146.150(e) in the case of the small group market or under applicable State law in the case of the large group market.

(4) *Termination of plan.* The issuer is ceasing to offer coverage in the market in accordance with paragraphs (c) and (d) of this section and applicable State law.

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the group health plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under § 146.150(c).

(6) *Association membership ceases.* For coverage made available in the small or large group market only through one or more bona fide associations, if the employer's membership in the association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor relating to any covered individual.

(c) *Discontinuing a particular product.* In any case in which an issuer decides to discontinue offering a particular product offered in the small or large group market, that product may be discontinued by the issuer in accordance with applicable State law in the particular market only if—

(1) The issuer provides notice in writing to each plan sponsor provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 days before the date the coverage will be discontinued;

(2) The issuer offers to each plan sponsor provided that particular product the option, on a guaranteed issue basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in that market; and

(3) In exercising the option to discontinue that product and in offering the option of coverage under paragraph (c)(2) of this section, the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(d) *Discontinuing all coverage.* An issuer may elect to discontinue offering all health insurance coverage in the small or large group market or both markets in a State in accordance with applicable State law only if—

(1) The issuer provides notice in writing to the applicable State authority and to each plan sponsor (and all participants and beneficiaries covered under the coverage) of the discontinuation at least 180 days prior to the date the coverage will be discontinued; and

(2) All health insurance policies issued or delivered for issuance in the State in the market (or markets) are discontinued and not renewed.

(e) *Prohibition on market reentry.* An issuer who elects to discontinue offering all health insurance coverage in a market (or markets) in a State as described in paragraph (d) of this section may not issue coverage in the market (or markets) and State involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(f) *Exception for uniform modification of coverage.* Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan in the—

(1) Large group market; and

(2) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with State law and is effective uniformly among group health plans with that product.

(g) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, the reference to ''plan sponsor'' is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

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[62 FR 16958, Apr. 8, 1997; 62 FR 31670, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 146.160 Disclosure of information.

(a) *General rule.* In connection with the offering of any health insurance coverage to a small employer, a health insurance issuer is required to—

(1) Make a reasonable disclosure to the employer, as part of its solicitation and sales materials, of the availability of information described in paragraph (b) of this section; and

(2) Upon request of the employer, provide that information to the employer.

(b) *Information described.* Subject to paragraph (d) of this section, information that must be provided under paragraph (a)(2) of this section is information concerning the following:

(1) Provisions of coverage relating to the following:

(i) The issuer's right to change premium rates and the factors that may affect changes in premium rates.

(ii) Renewability of coverage.

(iii) Any preexisting condition exclusion, including use of the alternative method of counting creditable coverage.

(iv) Any affiliation periods applied by HMOs.

(v) The geographic areas served by HMOs.

(2) The benefits and premiums available under all health insurance coverage for which the employer is qualified, under applicable State law. See § 146.150(b) through (f) for allowable limitations on product availability.

(c) *Form of information.* The information must be described in language that is understandable by the average small employer, with a level of detail that is sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage. This requirement is satisfied if the issuer provides each of the following with respect to each product offered:

(1) An outline of coverage. For purposes of this section, outline of coverage means a description of benefits in summary form.

(2) The rate or rating schedule that applies to the product (with and without the preexisting condition exclusion or affiliation period).

(3) The minimum employer contribution and group participation rules that apply to any particular type of coverage.

(4) In the case of a network plan, a map or listing of counties served.

(5) Any other information required by the State.

(d) *Exception.* An issuer is not required to disclose any information that is proprietary and trade secret information under applicable law.

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[62 FR 16958, Apr. 8, 1997, as amended at 62 FR 35906, July 2, 1997]

Subpart F—Exclusion of Plans and Enforcement

§ 146.180 Treatment of non-Federal governmental plans.

The plan sponsor of a non-Federal governmental plan may elect to be exempted from any or all of the requirements identified in paragraph (a) of this section with respect to any portion of its plan that is not provided through health insurance coverage, if the election complies with the requirements of paragraphs (b) and (c) of this section. The election remains in effect for the period described in paragraph (d) of this section.

(a) *Exemption from requirements.* The election described in this section exempts a non-Federal governmental plan from the following requirements:

(1) Limitations on preexisting condition exclusion periods (§ 146.111).

(2) Special enrollment periods for individuals and dependents (§ 146.117).

(3) Prohibitions against discriminating against individual participants and beneficiaries based on health status (§ 146.121).

(4) Standards relating to benefits for mothers and newborns (section 2704 of the PHS Act).

(5) Parity in the application of certain limits to mental health benefits (section 2705 of the PHS Act).

(b) *Form and manner of election.* (1) The election must be in writing.

(2) The election document must include as an attachment a copy of the notice described in paragraphs (f) and (g) of this section.

(3) The election document must state the name of the plan and the name and address of the plan administrator.

(4) The election document must either state that the plan does not include health insurance coverage, or identify which portion of the plan is not funded through insurance.

(5) The election must be made in conformity with all the plan sponsor's rules, including any public hearing, if required, and the election document must certify that the person signing the election document, including if applicable a third party plan administrator, is legally authorized to do so by the plan sponsor.

(6) The election document must be signed by the person described in paragraph (b)(5) of this section.

(c) *Timing of election.* (1) For plans not subject to collective bargaining agreements, the election must be received by HCFA by the day preceding the beginning date of the plan year.

(2) For plans provided under a collective bargaining agreement, the election must be received by HCFA no later than 30 days after—

(i) The date of the agreement between the governmental entity and union officials; or

(ii) If applicable, ratification of the agreement.

(3) HCFA may extend the deadlines specified under paragraphs (c)(1) and (c)(2) of this section for good cause.

(4) If the plan sponsor fails to file a timely election in accordance with paragraphs (c)(1) through (c)(3) of this section, the plan is subject to the requirements described in paragraph (a) of this section for the entire plan year, or, in the case of a plan provided under a collective bargaining agreement, for the term of the agreement.

(d) *Period of election.* An election under paragraph (a) of this section applies—

(1) For a single specified plan year; or

(2) In the case of a plan provided under a collective bargaining agreement, for the term of the agreement. (For purposes of this section, if a collective bargaining agreement expires during the bargaining process for a new agreement, and the parties agree that the prior bargaining agreement continues in effect until the new agreement takes effect, the ''term of the agreement'' is deemed to continue until the new agreement takes effect.)

(e) *Subsequent elections.* An election under this section may be extended through subsequent elections.

(f) *Notice to participants.* (1) A plan that makes the election described in this section notifies the participant of the election, and explains the consequences of the election. This notice must be provided—

(i) to each participant at the time of enrollment under the plan; and

(ii) To all participants on an annual basis.

(2) The notice shall be in writing, and must include the information specified in paragraph (g) of this section.

(3) The notice shall be provided to each participant individually.

(4) Subject to paragraph (g) of this section, the requirements of paragraphs (f)(1) through (f)(3) of this section are considered to have been met if the notice is prominently printed in the summary plan document, or equivalent document, and each participant receives a copy of that document at the time of enrollment and annually thereafter.

(g) *Notice content.* The notice must contain at least the following information:

(1) A statement that, in general, Federal law imposes upon group health plans the requirements described in paragraph (a) of this section (which must be individually described in the notice).

(2) A statement that Federal law gives the plan sponsor of a non-Federal governmental plan the right to exempt

the plan in whole or in part from the requirements described in paragraph (a) of this section, and that the plan sponsor has elected to do so.

(3) A statement identifying which parts of the plan are subject to the election, and each of the requirements of paragraph (a) of this section from which the plan sponsor has elected to be exempted.

(4) If the plan chooses to provide any of the protections of paragraph (a) of this section voluntarily, or is required to under State law, a statement identifying which protections apply.

(h) *Certification and disclosure of creditable coverage.* Notwithstanding an election under this section, a non-Federal governmental plan must provide for certification and disclosure of creditable coverage under the plan with respect to participants and their dependents in accordance with § 146.115.

(i) *Effect of failure to comply with election requirements.* (1) Subject to paragraph (i)(2) of this section, a plan's failure to comply with the requirements of paragraphs (f) through (h) of this section invalidates an election made under this section.

(2) Upon a finding by HCFA that a non-Federal governmental plan has failed to comply with the requirements of paragraphs (f) through (h) of this section, and has failed to correct the noncompliance within 30 days (as provided in § 146.184(d)(7)(iii)(B)), HCFA notifies the plan that its election has been invalidated and that it is subject to the requirements of this part.

(3) A non-Federal governmental plan described in paragraph (i)(2) of this section that fails to comply with the requirements of this part is subject to Federal enforcement by HCFA under § 146.184, including appropriate civil money penalties.

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[62 FR 16958, Apr. 8, 1997; 62 FR 31694, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 146.184 Enforcement.

(a) *Enforcement with respect to group health plans*—(1) *Scope.* In general, the requirements of the Health Insurance Portability and Accountability Act that apply to group health plans are contained in part 7 of subtitle B of title I of ERISA, and in subtitle K of the Internal Revenue Code. They are enforced by the Secretary of Labor under part 5 of subtitle B of title I of ERISA, and the Secretary of the Treasury under 26 U.S.C. 4980D. However, the provisions that apply to group health plans that are non-Federal governmental plans are contained in title XXVII of the PHS Act, and enforced by HCFA. The provisions of title XXVII that apply to health insurance issuers that offer coverage in connection with any group health plan are enforced in the first instance by the States. If HCFA determines under paragraph (b) of this section that a State is not substantially enforcing the provisions, HCFA enforces them under paragraph (d) of this section.

(2) *Non-Federal governmental plans.* Requirements of this part that apply to group health plans that are non-Federal governmental plans (sponsored by a State or local governmental entity) are enforced by HCFA, as provided in paragraph (d) of this section.

(b) *Enforcement with respect to health insurance issuers*—(1) *General rule—enforcement by State.* Except as provided in paragraph (b)(2) of this section, each State enforces the requirements of this part with respect to health insurance issuers that issue, sell, renew or offer health insurance coverage in the small or large group markets in the State.

(2) *Enforcement by HCFA.* HCFA enforces the provisions of this part with respect to health insurance issuers, using the procedures described in paragraph (d) of this section, only in the following circumstances:

(i) *State election.* If the State chooses not to enforce the Federal requirements.

(ii) *State failure to enforce.* If HCFA makes a determination under paragraph (c) of this section that a State has failed to substantially enforce one or more provisions of this part.

(c) *Determination by Administrator.* If HCFA receives information, through a complaint or any other means, that raises a question whether a State is substantially enforcing one or more provisions of this part, HCFA follows the procedures set forth in this section.

(1) *Verification of exhaustion.* HCFA makes a threshold determination of whether the individuals affected by the alleged failure to enforce have made a reasonable effort to exhaust any State remedies. This may involve informal contact with State officials about the questions raised.

(2) *Notice to the State.* If HCFA is satisfied that there is a reasonable question whether there has been a failure to substantially enforce, HCFA provides notice as specified in paragraph (c)(3) of this section, to the following State officials:

(i) The Governor or chief executive officer of the State.

(ii) The insurance commissioner or chief insurance regulatory official.

(iii) The official responsible for regulating HMOs, if different than paragraph (c)(2)(ii) of this section, but only if the alleged failure involves HMOs.

(3) *Form and content of notice.* The notice described in paragraph (c)(2) is in writing, and does the following:

(i) Identifies the provision or provisions of the statute and regulations that have allegedly been violated.

(ii) Describes the facts of the specific violations.

(iii) Explains that the consequence of a failure to substantially enforce any provisions is that HCFA enforces the provision in accordance with paragraph (d) of this section.

(iv) Advises the State that it has 45 days to respond to the notice, unless the time is extended as described in paragraph (c)(3) of this section, and that the response should include any information that the State wishes HCFA to consider in making the preliminary determination described in paragraph (c)(5) of this section.

(4) *Good cause.* The time for responding can be extended for good cause. Examples of good cause include an agreement between HCFA and the State that there should be a public hearing on the State's enforcement, or evidence that the State is undertaking expedited enforcement activities.

(5) *Preliminary determination.* If at the end of the 45-day period, and any extension, the State has not established to HCFA's satisfaction that it is substantially enforcing the provision or provisions described in the notice, HCFA takes the following actions:

(i) Consults with the officials described in paragraph (c)(1) of this section.

(ii) Notifies the State of HCFA's preliminary determination that the State has failed to enforce the provisions, and that the failure is continuing.

(iii) Permits the State a reasonable opportunity to show evidence of substantial enforcement.

(6) *Final determination.* If, after providing notice and the opportunity to enforce under paragraph (c)(5) of this section, HCFA finds that the failure to enforce has not been corrected, HCFA sends the State a written notice of that final determination. The notice—

(i) Identifies the provisions with respect to which HCFA is taking over enforcement;

(ii) States the effective date of HCFA's enforcement;

(iii) Informs the State of the mechanism for establishing in the future that it has corrected the failure, and has begun enforcement. This mechanism will include transition procedures for ending HCFA's enforcement.

(d) *Civil money penalties*—(1) *General rule.* If any health insurance issuer that is subject to HCFA's enforcement authority under paragraph (b)(2) of this section, or any non-Federal governmental plan (or employer that sponsors a non-Federal governmental plan) that is subject to HCFA's enforcement authority under paragraph (a)(2) of this section, fails to comply with any applicable requirement of this part, it may be subject to a civil money penalty as described in this paragraph (d).

(2) *Complaint.* Any person who is entitled to any right under this part, and who believes that the right is being denied as a result of any failure described in paragraph (d)(1) of this section, may file a complaint with HCFA. Based on the complaint, HCFA identifies which entities are potentially responsible for the violation, in accordance with paragraph (d)(3) of this section.

(3) *Determination of responsible entity.* If a failure to comply is established under this section, the responsible entity, as determined under this paragraph, is liable for the penalty. If the violation is due to a failure by—

(i) A health insurance issuer, the issuer is the responsible entity;

(ii) A group health plan that is a non-Federal governmental plan sponsored by a single employer, the employer is the responsible entity;

(iii) A group health plan that is a non-Federal governmental plan sponsored by two or more employers, the plan is the responsible entity.

(4) *Notice to responsible entities.* HCFA provides notice to the appropriate entity or entities identified under paragraph (d)(3) of this section that a complaint or other information has been received alleging a violation of this part. The notice—

(i) Describes the substance of any complaint or other allegation;

(ii) Provides 30 days for the responsible entity or entities to respond with additional information. This can include—

(A) Information refuting that there has been a violation;

(B) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation;

(C) Evidence of a previous record of compliance.

(5) *Notice to other regulators.* HCFA notifies the State if the alleged violation involves a health insurance issuer under its jurisdiction.

(6) *Notice of assessment.* If, based on the information provided in the complaint, as well as any information submitted by the entity or any other parties, HCFA proposes to assess a civil money penalty, HCFA sends written notice of assessment to the responsible entity or entities by certified mail, return receipt requested. The notice contains the following information:

(i) A reference to the provision that was violated.

(ii) The name or names of the individuals with respect to whom a violation occurred, with relevant identification numbers.

(iii) The facts that support the finding of a violation, and the initial date of the violation.

(iv) The amount of the proposed penalty as of the date of the notice.

(v) The basis for calculating the penalty, including consideration of prior compliance.

(vi) Instructions for responding to the notice, including—

(A) A specific statement of the respondent's right to a hearing; and

(B) A statement that failure to request a hearing within 30 days permits the imposition of the proposed penalty, without right of appeal.

(7) *Amount of penalty*—(i) *Maximum daily penalty.* The penalty cannot exceed $100 for each day, for each responsible entity, for each individual with respect to whom such a failure occurs.

(ii) *Standard for calculating daily penalty.* In calculating the amount of the penalty HCFA takes into account the responsible entity's previous record of compliance and the gravity of the violation.

(iii) *Limitations on penalties.* No civil money penalty is imposed:

(A) With respect to a period during which a failure existed, but none of the responsible entities knew, or exercising reasonable diligence would have known, that the failure existed.

(B) With respect to the period occurring immediately after the period described in paragraph (d)(7)(iii)(A) of this section, if the failure—

(*1*) Was due to reasonable cause and was not due to willful neglect; and

(*2*) Was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(C) The burden is on the responsible entity or entities to establish to the satisfaction of HCFA that none of the entities knew, or exercising reasonable diligence could have known, that the failure existed.

(8) *Hearings*—(i) *Right to a hearing.* Any entity against which a penalty is assessed may request a hearing by HCFA. The request must be in writing, and must be postmarked within 30 days after the date the notice of assessment is issued.

(ii) *Failure to request a hearing.* If no hearing is requested under this paragraph, the notice of assessment constitutes a final order that is not subject to appeal.

(iii) *Parties to the hearing.* Parties to the hearing include any responsible entities, as well as the party who filed

the complaint. An informational notice is also sent to the State, or to the Secretaries of Labor and the Treasury, as appropriate.

(iv) *Initial agency decision.* The initial agency decision is made by an administrative law judge. The decision is made on the record according to section 554 of title 5, United States Code. The decision becomes a final, appealable order after 30 days, unless it is modified in accordance with paragraph (d)(8)(v) of this section.

(v) *Review by HCFA.* HCFA may modify or vacate the initial agency decision. Notice of intent to modify or vacate the decision is issued to the parties within 30 days after the date of the decision of the administrative law judge.

(9) *Judicial review*—(i) *Filing of action for review.* Any entity against whom a final order imposing a civil money penalty is entered in accordance with paragraph (d)(8) of this section may obtain review in the United States District Court for any district in which the entity is located or the United States District Court for the District of Columbia by—

(A) Filing a notice of appeal in that court within 30 days from the date of a final order; and

(B) Simultaneously sending a copy of the notice of appeal by registered mail to HCFA.

(ii) *Certification of administrative record.* HCFA will promptly certify and file with the court the record upon which the penalty was imposed.

(iii) *Standard of review.* The findings of HCFA may not be set aside unless they are found to be unsupported by substantial evidence, as provided by Section 706(2) (E) of title 5, United States Code.

(iv) *Appeal.* Any final decision, order or judgment of the district court concerning the Administrator's review is subject to appeal as provided in Chapter 83 of Title 28, United States Code.

(10) *Failure to pay assessment, maintenance of action*—(i) *Failure to pay assessment.* If any entity fails to pay an assessment after it becomes a final order under paragraphs (d)(7)(i)(A) or (d)(7)(iii) of this section, or after the court has entered final judgment in favor of HCFA, HCFA refers the matter to the Attorney General, who brings an action in the appropriate United States district court to recover the amount assessed.

(ii) *Final order not subject to review.* In an action brought under paragraph (d)(10)(i) of this section, the validity and appropriateness of the final order described in paragraphs (d)(7)(i)(A) or (d)(7)(iii) of this section is not subject to review.

(11) *Use of penalty funds.* (i) Any funds collected under this section will be paid to HCFA or other office imposing the penalty.

(ii) The funds will be available without appropriation and until expended.

(iii) The funds may only be used for the purpose of enforcing the provisions with respect to which the penalty was imposed.

PART 147 [RESERVED]

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

Subpart A—General Provisions

Sec.

Subpart B—Requirements Relating to Access and Renewability of Coverage

Subpart C [Reserved]

Subpart D—Enforcement; Penalties; Preemption